

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

DAYTON AREA CHAMBER OF  
COMMERCE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

**No. 3:23-cv-00156-MJN-PBS**

**Judge Michael J. Newman**

**Magistrate Judge Peter B. Silvain, Jr.**

**MOTION OF PUBLIC CITIZEN, PATIENTS FOR AFFORDABLE DRUGS NOW,  
DOCTORS FOR AMERICA, PROTECT OUR CARE, AND FAMILIES USA  
FOR LEAVE TO FILE A MEMORANDUM AS AMICI CURIAE IN SUPPORT OF  
DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION  
TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, and Families USA respectfully move for leave to file a memorandum as amici curiae in support of the defendants' opposition to the plaintiffs' motion for summary judgment and cross-motion. Counsel for amici has conferred with counsel for the plaintiffs and the defendants. The plaintiffs and defendants consent to this motion.

A. Movants are five non-profit organizations with expertise in public health and with longstanding interests in patients' access to health care, including affordable medicines.

Public Citizen is a non-profit consumer advocacy organization with members and supporters in all 50 states. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including ensuring that patients' and consumers' interests are protected in the resolution of the many legal and regulatory issues posed by prescription drugs and

medical devices. A central concern of Public Citizen is protecting and expanding access to affordable medicines for consumers, both domestically and globally. As part of its longstanding commitment to protecting access to medications, Public Citizen has advocated for enforcement of the antitrust laws against brand-name drug manufacturers that seek to exclude generic competition. And through its Access to Medicines program, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower pharmaceutical prices. Public Citizen has provided technical assistance concerning patent rules and access to medicines to dozens of governments as well as to international organizations.

Patients For Affordable Drugs Now (P4ADNow) is the only national patient advocacy organization focused exclusively on lowering prescription drug prices. P4ADNow is bipartisan, independent, and does not accept funding from any organizations that profit from the development or distribution of prescription drugs. Since its founding, P4ADNow has advocated to empower Medicare to negotiate prices directly with pharmaceutical companies for a better deal for both patients and taxpayers in the United States. P4ADNow is pleased to sign an amicus memorandum to protect the Inflation Reduction Act's drug price negotiation program—an historic measure which will strengthen the health, well-being, and financial security of individuals and families across the country.

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics on the pressing issues of the day to improve the health of its patients, communities, and nation. Doctors for America is one of the only non-partisan, non-profit, non-trade organizations of medical professionals working on patients' behalf in the area of drug affordability. It is continuously working to improve access to equitable, affordable, high-quality health care for patients across the country. For this reason, Doctors for America has a longstanding

history of working to improve drug affordability by advocating for legislative, regulatory, and judicial changes to ensure patients can access their life sustaining treatments.

Protect Our Care, a fiscally sponsored project of the New Venture Fund, is dedicated to making high-quality, affordable, and equitable health care a right, and not a privilege, for everyone in America. Protect Our Care educates the public, influences policy, supports health care champions, and holds lawmakers accountable. Protect Our Care supported the development and enactment of the Inflation Reduction Act's provisions to make prescription drugs more affordable, including the Medicare drug price negotiation program. Protect Our Care is committed to the successful implementation of the law, including by defeating legal attacks, to ensure seniors and taxpayers benefit from more affordable prescription drugs.

Families USA is a non-partisan voice for health care consumers and is dedicated to achieving high-quality, affordable health care and improved health for all. On behalf of health care consumers, working people, and patients, Families USA has advocated for decades for legislation and rulemaking that improves the accessibility and affordability of prescription drugs. Since the creation of Medicare Part D, Families USA has believed that ensuring drug affordability should be a key part of the program and has urged policymakers to explore the root causes of high and irrational drug prices and to tackle the complex network of abusive practices that underpin the American pharmaceutical market.

**B.** The plaintiffs' motion for summary judgment seeks to invalidate the drug price negotiation program, 42 U.S.C. § 1320f *et seq.*, enacted as part of the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818. The program seeks to lower the high cost of prescription drugs made available to seniors enrolled in Medicare by providing a mechanism for the federal government and drug manufacturers to negotiate drug prices available to enrollees

beginning in 2026. Plaintiffs' motion, if granted, would prevent defendants from negotiating lower drug prices for the Medicare program and deny enrollees the benefits of lower prescription drug costs.

The proposed amicus memorandum addresses two points. First, the proposed memorandum traces Congress's prior efforts to improve Medicare enrollees' access to provider-administered medications and prescription drugs and explains how those efforts have failed to prevent significant increases in the drug prices that have left many people unable to afford their out-of-pocket payments. As the proposed memorandum explains, many Medicare enrollees consequently forgo medications that they cannot afford or sacrifice other essential needs in order to pay for their medications. The drug price negotiation program addresses affordability by providing a means for negotiating lower drug prices and thereby improving seniors' access to Medicare-covered drugs.

Second, the proposed memorandum responds to plaintiffs' argument that the drug price negotiation program violates the Due Process Clause because, plaintiffs claim, drug companies face the risk of being required to sell their product at confiscatory rates. The memorandum demonstrates that, contrary to plaintiffs' contention, the drug price negotiation program does not impose price controls on drug companies akin to rate regulation of public utilities because, unlike public utilities, drug companies voluntarily opt into Medicare to obtain the financial benefits that flow to drug companies from federal subsidies to providers and patients, and, unlike public utilities, a drug company have the right to opt out of Medicare before negotiated prices take effect. In addition, the memorandum explains that plaintiffs are wrong to suggest that drug companies are deprived of a property interest because negotiated prices will be "below market."

In these circumstances, where a proper understanding of the operation of Medicare and the drug price negotiation program are central to the questions presented in this case, movants believe that the information and arguments set out in the proposed amicus memorandum by organizations focused on the public interest and with expertise on this topic will assist this Court in resolving the pending motion.

The proposed memorandum is attached to this motion. A proposed order is also attached.

### **CONCLUSION**

The Court should grant this motion for leave to file an amicus curiae memorandum.

December 19, 2023

Respectfully submitted,

/s/ Lauren Bateman

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